Chiesi TOTAL care℠

Prescription/Nursing Order Form & Statement of Medical Necessity

ELFABRIO® (pegunigalsidase alfa-iwxj)

PATIENT INFORMATION

Patient Name (Last, First) _____

Social Security # _____ - _____ - _____ Sex: ☐ Male ☐ Female Date of Birth _____/_____/_____ (mm/dd/yyyy)

Address _____ City _____ State _____ ZIP _____

Primary Phone (Required) _____ Cell Phone _____ Language: ☐ English ☐ Other _____

Please attach copies of patient insurance and prescription cards—front and back.

MEDICAL INFORMATION

Diagnosis: ☐ Fabry (-Anderson) Disease ICD-10-CM E75.21

Height _____ inches or _____ cm Weight _____ lb or _____ kg Allergies: ☐ None ☐ Specify _____

Methods of Diagnosis (check all that apply):

☐ Enzyme Assay ☐ Genetic Testing ☐ Tissue Biopsy ☐ Other _____

Prior treatment and dose: _____ Last date of prior treatment and dose: _____

Please attach copies of medical history/physical summary, most recent alpha-galactosidase A (alpha-Gal A), genotype, plasma globotriaosylsphingosine (lyso-Gb3), current medications, and allergies.

ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ) 20 mg/10 mL PRESCRIPTION

Dosage — Elfabrio (pegunigalsidase alfa-iwxj) 20 mg/10 mL vial

Total Dose (mg*) _____ Route of Administration IV _____ Frequency* _____

Number of Refills† _____ Infusion Rate (mL/hour) _____

*The recommended dosage is 1 mg/kg of body weight every 2 weeks, administered as an intravenous infusion.

†Quantity sufficient for a 28-day supply.

Please list any additional treatment information, including follow-up evaluations: _____

_____

SITE OF SERVICE

Preferred Acquisitions Channel:

☐ Buy and Bill
(If site does not allow white bagging, send the form directly to EVERSANA®.)

☐ Specialty Pharmacy to Bill
(Please select one of the below specialty pharmacies and send the prescription to them directly.)

☐ Other _____

○ CVS Specialty Pharmacy
PH: 1-800-506-6439 (HAE/LSD is Option 5)
FAX: 1-855-365-8111

○ EVERSANA Life Science Services
PH: 1-833-656-1056
FAX: 1-636-355-3610

○ Orsini Specialty Pharmacy
PH: 1-800-240-9572
FAX: 1-847-427-7976

Preferred Site of Infusion:

Site of Infusion _____

Contact Person _____

NURSING ORDERS

- The recommended dose is 1 mg/kg of body weight
  - – Number of vials per infusion (round up to a whole # if the calculated # of vials is a fraction) = Patient dose (mg) ÷ 20 mg (contents of 1 vial)
  - – Prior to adding the volume of Elfabrio required for the dose, remove the equal volume of 0.9% Sodium Chloride Injection from the infusion bag
  - – Infusion duration is calculated individually, with a minimum infusion duration of 90 minutes

Patient's Actual Weight	Total Infusion Volume
up to 70 kg	☐ 150 mL 0.9% NaCl
70 - 100 kg	☐ 250 mL 0.9% NaCl
>100 kg	☐ 500 mL 0.9% NaCl

- Infusion rate may be increased if the patient tolerates the initial 4-6 Elfabrio infusions. Infusion rate may be slowed in case of hypersensitivity reaction or an infusion-associated reaction

☐ Monitor vital signs at the start of the infusion, at the end of the infusion and observation period, and PRN _____

- Intravenous access and flush orders:
  - ☐ Peripheral IV line:
    - – Before Infusion: 0.9% Sodium Chloride Injection 3-5 mL
    - – After Infusion: 0.9% Sodium Chloride Injection 3-5 mL
  - ☐ Implanted port/Central line:
    - – Before Infusion: 0.9% Sodium Chloride Injection 5-10 mL
    - – After Infusion: 0.9% Sodium Chloride Injection 5-10 mL and Heparin (100 units/mL) 5 mL
  - ☐ Other flush orders _____

If a severe reaction occurs, immediately discontinue Elfabrio, initiate appropriate medical care, and contact the prescriber. If a mild to moderate reaction occurs, consider slowing or temporarily withholding Elfabrio, initiate appropriate medical care, and contact the prescriber.

(Please continue on following pages—signature required) — Please see Important Safety Information for Elfabrio, including Boxed Warning, on page 3 and accompanying Full Prescribing Information.

Prescription/Nursing Order Form & Statement of Medical Necessity (cont'd)

MEDICATION ORDERS

Select medication(s) needed for this administration:
Oral (PO) medications to be obtained and self-administered by patient

☐ EMLA® Cream
Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ○ Premedication ◉ PRN Allergic Reaction

☐ Methylprednisolone
○ 40 mg ICP ○ 125 mg ICP ◉ Other Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ○ Premedication ◉ PRN Allergic Reaction

☐ Acetaminophen
Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ◉ Premedication ○ PRN Allergic Reaction

☐ Famotidine
◉ 20 mg ICP ○ 40 mg ICP ○ Other Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ○ Premedication ◉ PRN Allergic Reaction

☐ Diphenhydramine (50 mg/mL)
○ 25 mg ICP ○ 50 mg ICP ◉ Other Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ◉ Premedication ○ PRN Allergic Reaction

☐ Albuterol sulfate inhalation aerosol for oral inhalation
Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ○ Premedication ◉ PRN Allergic Reaction

☐ Epinephrine auto-injector
Dose _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ○ Premedication ◉ PRN Allergic Reaction

☐ Other: _____
Dose _____ Route _____
Physician Directions _____
Quantity _____ Refills _____
Choose One: ◉ Premedication ○ PRN Allergic Reaction

Additional orders: _____

MANDATORY OFFICE CHECKLIST (Home Infusion Only)

☑ Please confirm that you have completed each of the following steps:

☑ The patient has had successful infusions in an outpatient setting

☑ The patient is medically stable and safe for home infusion therapy

☑ The patient has been prescribed an epinephrine auto-injector

☑ The patient lives in an area where emergency medical services are available

PHYSICIAN/OFFICE INFORMATION

Prescriber's Name (Print) _____ Practice/Group Name _____
Address _____ Suite _____
City _____ State _____ ZIP _____
Office Contact Person _____
Office Phone _____ Office Fax _____
License # _____ NPI # _____
Preferred Medical Facility (Name, Phone) _____
List of Facilities Where Physician Has Privileges _____

By signing below, I certify that I am the prescribing provider mentioned above, that I am part of the Chiesi Total Care℠ Program, that the therapy described above is medically necessary, and that all the medical necessity information is true, accurate, and complete. The patient's records contain supporting documentation that substantiates the utilization and medical necessity of the products marked above. I provide permission to use my personal information and the personal information of the patient provided above to facilitate this request and complete any regulatory or legal requirements associated with this request. I understand that the personal information provided herein may be shared with Chiesi, successors, and their agents and service providers as needed to support this request. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary for the Chiesi Total Care Program and/or their agents and service providers. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian. If my patient is eligible for free product, I understand that receiving free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; nor may I bill any payer for administration of such product. I understand that any falsification, omission, or concealment of material fact may result in criminal liability.

X _____
Licensed Prescriber Signature (required – no stamps)

Printed Name _____ Date _____

ATTENTION: E-prescribe or use the official state prescription form where required by state law. No stamped signatures or signing on behalf of the prescriber.

Indication

Elfabrio® (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Elfabrio administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue Elfabrio immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Elfabrio may be considered.

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (IARs), and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels).

The most common adverse reactions (≥15%) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Please see accompanying Full Prescribing Information for Elfabrio.

Questions? Chiesi Total Care℠ is here to help!
Please contact Chiesi Total Care at 1-833-656-1056 if you have questions regarding this form.

For more information, visit elfabrio.com.

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